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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,506	04/12/2004	Carl G. Hellerqvist	22100-0202 (49530-299673)	3571
23370 7590 01/31/2007 JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			EXAMINER LI, RUIXIANG	
			ART UNIT	PAPER NUMBER
			1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/823,506	HELLERQVIST ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 82, 83, 85-89, 97-100 and 102-105 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 82, 83, 85-89, 97-100, 102-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicants' response filed on 11/17/2006 has been entered in full. Claims 84 and 101 are canceled. New claims 104 and 105 are added. Claims 82, 83, 85-89, 97-100, and 102-105 are pending and currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The objection to the specification is withdrawn in view of the amendment to the specification.

The rejection of claims 82, 85-89, 98, 99, 102, and 103 under 35 U.S.C. 112, second paragraph, is withdrawn in view of amended claims.

The objection to claims 82, 83, 85-89, 97-100, 102, and 103 for minor informalities is withdrawn in view of amended claims.

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Claim Rejections Under 35 U.S.C. §112, 1st Paragraph (Enablement)

The rejection of claims 82, 83, 85-89, 97-100, 102, and 103 under 35 U.S.C. 112, first paragraph for scope of enablement is maintained. New claims 104 and 105 are also rejected on the same basis.

Applicants argue that amended claims 82 and 97 recite "a mammalian GBS toxin receptor or a polypeptide fragment thereof, wherein the GBS toxin receptor has at least about 86% identity to SEQ ID NO: 8". Applicants argue that the amended claims recite structural characteristics of a GBS toxin receptors or a fragment thereof, as disclosed in the specification. Applicants argue that the application enables one of ordinary skill in the art in the field of the present application to make and use antibodies as claimed in claim 82 and 97.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reason. The amended claims are still broad because the claims encompass GBS toxin receptor variants/homologues and their fragments. There are no structural and functional limitations for the fragment of the GBS toxin receptor. Since a fragment of a polypeptide can include a single amino acid, the claims can be reasonably interpreted to include any substantially purified polypeptide that is smaller in size than the polypeptide of SEQ ID NO: 8. Applicants have taught that human and sheep GBS toxin receptors set forth in SEQ ID NO: 4 and SEQ ID NO: 8, respectively. However, the instant disclosure fails to provide sufficient guidance and/or working examples on how to make and use the genus of GBS toxin receptor variants that have at least 86%

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identity to SEQ ID NO: 8 or fragments thereof. Since the disclosure fails to describe the conserved structure for the binding domain of GBS toxin receptor, it is unpredictable whether a fragment of GBS toxin receptor, for example, SEQ ID NO: 8 maintains the activity of the full-length receptor. It would require large quantities of experimentation to practice the claimed invention. Thus, it would require undue experimentation for one skilled in the art to make and use the GBS toxin receptors and fragments thereof. Consequently, it would require undue experimentation for one skilled in the art to make and use an antibody or a fragment thereof that binds the GBS toxin receptors and fragments thereof.

Applicants argue that it is not necessary to for a fragment of a GBS toxin receptor to maintain activity of the full-length receptor in order to make and use the claimed antibodies or compositions for detection of such a fragment. This is not persuasive because a fragment encompasses a polypeptide that is smaller in size than the polypeptide of SEQ ID NO: 8, including a single amino acid. If a fragment does not have the binding domain or does not have a GBS toxin receptor activity, one skilled in the art would not know how to use the fragment and thus an antibody that binds the fragment.

Applicants argue that an immunogenic fragment of a GBS toxin receptor can be used to generate the antibodies. Applicants also argue that one of skill in the art in the field of the present application would be able to obtain a composition for detection of a GBS toxin receptor or a fragment thereof, for example, by screening for compounds capable

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of blocking antibody binding or GBS toxin binding to the GBS toxin receptors. This is not found to be persuasive because the instant claims do not limit the fragment to an immunogenic fragment. An immunogenic fragment is useful when it is used to generate an antibody that binds to the full-length GBS toxin receptor. Thus, one skilled in the art would not know how to use an antibody that binds to a fragment, where the fragment does not have a specific biological or binding activity. Moreover, screening for compounds capable of blocking antibody binding or GBS toxin binding to the GBS toxin receptors does not necessarily obtain a composition for detection of a GBS toxin receptor fragment because there is no requirement that the fragment recited in the claims possess a binding domain of GBS toxin receptor.

Moreover, claim 97 is drawn to a composition comprising a reagent for detection of GBS toxin receptor or the fragment thereof. There are no structural and functional limitations for the reagent. There is no disclosure of the structural and functional characteristics of the recited reagent and the disclosure does not provide sufficient guidance and/or working examples regarding how to make the reagent. Thus, it would require undue experimentation for one skilled in the art to make and use the reagents.

Claim Rejections Under 35 U.S.C. §112, 1st Paragraph (Written Description)

The rejection of claims 82, 83, 85-89, 97-100, 102, and 103 under 35 U.S.C. 112, first paragraph for written description is maintained. New claims 104 and 105 are also rejected on the same basis.

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Applicants argue that amended claims 82 and 97 recite "a mammalian GBS toxin receptor or a polypeptide fragment thereof, wherein the GBS toxin receptor has at least about 86% identity to SEQ ID NO: 8". Applicants argue that the amended claims recite distinguishing features of a genus of GBS toxin receptors or fragments thereof disclosed in the specification.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the instant disclosure of GBS toxin receptors set forth in SEQ ID NOS: 4 and 8 does not adequately support the scope of the genus of GBS toxin receptors and fragments thereof encompassed in the claims. The disclosure fails to provide a representative number of GBS toxin receptors that has at least about 86% identity to SEQ ID NO: 8. Moreover, no structural and functional limitations are recited in the claims for the fragments of the GBS toxin receptors that have at least about 86% identity to SEQ ID NO: 8.

Moreover, as noted in the previous office action, claim 97 recites a composition comprising a reagent for detection of GBS toxin receptor or the fragment thereof. The claim does not require that the reagent possess any particular conserved structure or disclosed distinguishing feature. The disclosure does not provide adequate description of the partial structure, physical and/or chemical properties, functional characteristics of the recited reagent. One skilled in the art would not recognize from the disclosure that the applicant was in possession of a composition comprising such a reagent.

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Finally, Applicants' response fails to point out where in the specification the support for new claim 105 exists. It does not appear that Applicants were in possession an isolated antibody that recognizes a mammalian GBS toxin receptor from an animal or a human.

Accordingly, due to the breadth of the genus of GBS toxin receptors and fragments thereof and lack of the definitive structural or functional features of the genus of the GBS toxin receptor and fragments thereof, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of GBS toxin receptors and fragments thereof and thus the antibodies that bind to the GBS toxin receptors and fragments thereof.

Claim Rejections under 35 USC § 112, 2nd paragraph

The rejection of claim 97 under 35 U.S.C. 112, second paragraph set forth in the previous office action is maintained.

Applicants argue that the term "reagent" in relation to detection of GBS toxin receptor is defined in the specification on page 41, lines 28-33. This is not found to be persuasive because the specification only provides exemplary reagents for the term. Since the specification does not provide an unambiguous definition for the term, the claim is indefinite.

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Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Primary Examiner
January 29, 2007

RUIXIANG LI, PH.D.
PRIMARY EXAMINER